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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,292	04/29/2006	Zhiqiang Gao	4276-104	8044

23448 7590 05/20/2008
INTELLECTUAL PROPERTY / TECHNOLOGY LAW
PO BOX 14329
RESEARCH TRIANGLE PARK, NC 27709

EXAMINER

GITOMER, RALPH J

ART UNIT	PAPER NUMBER
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1657

MAIL DATE	DELIVERY MODE
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05/20/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/577,292	Applicant(s) GAO ET AL.	
	Examiner Ralph Gitomer	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 and 45 is/are pending in the application.
- 4a) Of the above claim(s) 1,3,5-11 and 19-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,4,12-18 and 45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/15/07, 9/22/06, 8/29/06, 5/30/06</u> . | 6) <input type="checkbox"/> Other: _____ |

Applicant's election without traverse of Group II, claims 2, 4, 12-18, 45, in the reply filed on 2/17/08 is acknowledged.

A reading of the specification reveals the point of novelty may reside in making vinylferrocene acrylamide copolymers for glucose sensors where the ferrocene does not interfere with polymerization while in sufficiently high concentration. The size of the ferrocene does not appear to be of any functional consequence.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2, 4, 12-18, 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Rauh in view of Bu.

Rauh (5,922,183) entitled "Metal Oxide Matrix Biosensors" teaches in column 4, a thin film containing amorphous hydrous metal oxides including Ti, Zr, Ru, Pd, Pt, Zr, Ti. Rh. In column 8 last paragraph bridging to column 9, electron mediators can be co-immobilized into the matrix and include ferrocene and derivatives. The film is used for determining glucose. See the claims.

The claims differ from Rauh in that they specify the matrix is an acrylamide polymer.

Bu (Anal Chem) entitled "Modification of Ferrocene Containing Redox Gel Sensor Performance by Copolymerization of Charged Monomers" teaches on page 3951 column 1 first paragraph, a glucose determining electrode with glucose oxidase and ferrocene formed by copolymerization of vinylferrocene hydroxypropyl cyclodextrin inclusion complex, acrylamide and N,N'-methylenebis(acrylamide). On page 3852 column 1 first paragraph polyvinyl ferrocene is shown.

It would have been obvious to one of ordinary skill in the art at the time of the invention to employ the components of a glucose biosensor as taught by Rauh in a polymeric matrix such as that taught by Bu because polymeric matrices are conventional in this art and Bu teaches the same types of components in the matrix for the same function as claimed. Note that the amorphous oxides in Rauh would be nanoparticles. And Bu teaches the same polymer matrix as claimed with the same glucose oxidase and sufficient ferrocene to function as a glucose sensor.

Claims 2, 4, 12-18, 45 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for specific electron mediators, does not reasonably provide enablement for "an electrochemical activator". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In claim 12 the terms "an electrochemical activator " lack enablement as it would require one of ordinary skill in this art undue experimentation to determine which would work in the instant invention.

The entire scope of the claims has not been enabled because:

1. Quantity of experimentation necessary would be undue because of the large proportion of inoperative compounds claimed.
2. Amount of direction or guidance presented is insufficient to predict which substances encompassed by the claims would work.
3. Presence of working examples are only for specific substances and extension to other compounds has not been specifically taught or suggested.
4. The nature of the invention is complex and unpredictable.
5. State of the prior art indicates that most related substances are not effective for the claimed functions.
6. Level of predictability of the art is very unpredictable.
7. Breadth of the claims encompasses an innumerable number of compounds.
8. The level of one of ordinary skill in this art is variable.

Art Unit: 1657

In re Wands, 858 F.2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 4, 12-18, 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

Claim 12 contains improper Markush terminology. And “electrochemical activator” is not understood in context. In claim 13 “capable of” renders the claim indefinite, the function of the mediator must be positively recited. In claim 15 the units are not understood.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The abstract of the disclosure is objected to because it is not directed to the elected invention. Correction is required. See MPEP § 608.01(b).

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Bu (Anal Chem) teaches sensors with polyacrylamide and vinylferrocene and glucose oxidase copolymerized.

Kracklauer (4,341,881) teaches polymer films.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ralph Gitomer/
Primary Examiner, Art Unit 1657

Ralph Gitomer
Primary Examiner
Art Unit 1657